

made to reflect a change in the *Agenda* portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Olga I. Claudio, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, 301-796-7608, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of February 7, 2011, FDA announced that a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee would be held on March 17 and 18, 2011. On page 6625, in the second column, in the last paragraph, in the first and second sentences, the "for the NovoTTF-100A Treatment Kit, sponsored by Hogan Lovells US LLP for NovoCure, Ltd. The NovoTTF-100A Treatment Kit" portion of the document is changed to read as follows: "for the NovoTTF-100A System, sponsored by NovoCure, Ltd. The NovoTTF-100A System".

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5285 Filed 3-8-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2010-E-0483 and FDA-2010-E-0484]

### Determination of Regulatory Review Period for Purposes of Patent Extension; AMPYRA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for AMPYRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>.

Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these Acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product AMPYRA (dalfampridine). AMPYRA is indicated to improve walking in patients with multiple sclerosis. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for AMPYRA (U.S. Patent Nos. 5,370,879 and 5,540,938) from Elan Pharma International Ltd., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term

restoration. In a letter dated September 30, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMPYRA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AMPYRA is 9,845 days. Of this time, 9,569 days occurred during the testing phase of the regulatory review period, while 276 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 10, 1983. The applicant claims January 1, 1980, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was initially placed on clinical hold. The applicant was informed that the investigational studies were allowed to proceed on February 10, 1983, the effective date of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 22, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for AMPYRA (NDA 22-250) was submitted on April 22, 2009.

3. *The date the application was approved:* January 22, 2010. FDA has verified the applicant's claim that NDA 22-250 was approved on January 22, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,827 and 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments and ask for a redetermination by May 9, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 5, 2011. To meet its burden, the petition must contain sufficient facts

to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 14, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011-5312 Filed 3-8-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-E-0332]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; CERVARIX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CERVARIX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51,

rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product CERVARIX (human papillomavirus bivalent (types 16 and 18) vaccine). CERVARIX is indicated for prevention of the following diseases caused by oncogenic human papillomavirus types 16 and 18: cervical cancer; cervical intraepithelial neoplasia grade 2 or sores and adenocarcinoma in situ; and cervical intraepithelial neoplasia grade 1. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CERVARIX (U.S. Patent No. 7,351,533) from MedImmune, LLC., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 26, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of

CERVARIX represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CERVARIX is 4,027 days. Of this time, 3,094 days occurred during the testing phase of the regulatory review period, while 933 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 9, 1998. The applicant claims September 8, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 9, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 29, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for CERVARIX (BLA 125259/0) was submitted on March 29, 2007.

3. *The date the application was approved:* October 16, 2009. FDA has verified the applicant's claim that BLA 125259/0 was approved on October 16, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 562 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments and ask for a redetermination by May 9, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 5, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written